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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,545	07/16/2003	Lars Olson	1522-1001-1	5943

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,545	OLSON ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above claim(s) *20-23 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720200.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 15-32 are pending.

Applicant's amendment canceling claims 1-13 and adding new claims 15-32, amendments to the specification, submission of a new ADS, and replacement of Figure 1, in a communication filed 9/8/2006 is acknowledged.

Applicant has introduced new claims 20-23 and 29-32 which are directed to a method for diagnosing Parkinson's disease. These claims are directed to the subject matter of claim 14 (Group II as defined in the restriction requirement mailed on 2/8/2006), which was cancelled in a preliminary amendment filed 2/17/2006, prior to examination on the merits of the elected invention (i.e., Group I as defined in the restriction requirement mailed on 2/8/2006). New claims 20-23 and 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 2/17/2006.

New claims 15-19 and 24-28 are directed to the elected subject matter (i.e., nucleic acids comprising SEQ ID NO: 1-7 and kits comprising said nucleic acids). Thus, claims 15-19 and 24-28 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

1. The objection made to the title of the invention is hereby withdrawn in view of Applicant's amendment of the title.

2. The specification remains objected for not complying with sequence rules. As previously indicated, while Figures 2-4 display sequences, neither the drawings nor the Brief Description of the

Drawings indicate the corresponding sequence identifiers. Applicant argues that Figures 2-4 refer to sequences already recited in the Sequence Listing or found in public databases. Thus, Applicant requests withdrawal of the objection. Arguments have been fully considered but are not deemed persuasive. As indicated in 37 CFR 1.821(d), where the description or claims of a patent application discuss a sequence that is set forth in the Sequence Listing, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or the claims, even if the sequence is also embedded in the text of the description or claims. In the instant case, the drawings are part of the specification and they disclose a sequence. The Brief Description of the Drawings section discusses the sequences of Figures 2-4. Thus, according to 37 CFR 1.821(d), reference to these sequences must be made by using the corresponding sequence identifier. As previously indicated, this objection can be overcome by either placing a sequence identifier in front of the sequences shown in Figures 2-4, or by inserting the corresponding sequence identifiers in the Brief Description of the Drawings section. Appropriate correction is required.

Oath/Declaration

3. The oath or declaration was found defective for providing an incorrect filing date for U.S. Application No. 09/720200. In view of Applicant's submission of a new ADS with the correct filing date for U.S. Application No. 09/720200, this objection is hereby withdrawn.

Drawings

4. In view of Applicant's submission of a replacement of Figure 1, the objection to the drawings is hereby withdrawn.

Claim Objections

5. In view of Applicant's cancellation of claims 1-4, 6-7, 9, 11, 13, the objection of said claims due to the recitation of "nucleotide" is hereby withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 2, 6, and 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of Applicant's cancellation of the instant claims, this rejection is hereby withdrawn.

8. New claims 15-19 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

9. Claim 15, 18-19, 24, 27-28 (claims 15-17 and 25-26 dependent thereon) are indefinite in the recitation of "nucleic acid sequence ....wherein said nucleic acid triggers.." and "nucleic acid according to claim 15/24" for the following reasons. Claims 15 and 24 are directed to nucleic acid sequences. Thus, there is no antecedent basis for the nucleic acid (molecule) recited in those claims. For examination purposes, it will be assumed that claims 15 and 24 are directed to nucleic acids and not nucleic acid sequences. Correction is required.

10. Claims 16-17 are indefinite in the recitation of "the ...sequence ...according to claim 15, further comprising at least ...consecutive bases...." as these limitations broaden the scope of claim 15. Claim 15 recites "consisting of one or more of SEQ ID NO: 1-7". Since the term "consisting" is considered closed language, the nucleic acid sequences of claim 15 are limited to nucleic acid sequences consisting of one of SEQ ID NO: 1-7, or combinations thereof which meet the "one or more of SEQ ID NO: 1-7"

limitation recited. Thus, the nucleic acid sequences of claim 15 cannot have other bases beyond those of SEQ ID NO: 1-7. For examination purposes, no patentable weight will be given to the term "further comprising at least ...consecutive bases....". Claims 16-17 will be considered duplicates of claim 15. Correction is required.

11. Claim 26 is indefinite in the recitation of "the....sequence.....according to claim 25, wherein the sequence is SEQ ID NO: 3" for the following reasons. Claim 25, from which claim 26 depends, is limited to the sequence of SEQ ID NO: 6 and it does not encompass SEQ ID NO: 3. Thus, claim 26 does not further limit claim 25. For examination purposes, it will be assumed that claim 26 is dependent upon claim 24. Correction is required.

Claim Rejections - 35 USC § 101

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claim 12 was rejected under 35 U.S.C. 101 because the instant claim was directed to non-statutory subject matter. In view of Applicant's cancellation of claim 12, this rejection is hereby withdrawn.

14. New claims 15-18, 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is necessitated by amendment and is applied to new claims 15-18, 24-26 for the reasons previously indicated regarding claim 12 and those set forth below.

The instant claims are directed to nucleic acid sequences. As known in the art, nucleic acid sequences are graphical representations of the order in which nucleotides are arranged in a nucleic acid molecule. Since a sequence is neither a product nor a method, the instant claims are directed to non-

statutory matter. For examination purposes, it will be assumed that the claims are directed to nucleic acids.

15. Claims 1-13 were rejected under 35 U.S.C. 101 as lacking either a substantial and specific asserted utility or a well established utility, and also under 112, first paragraph, as one of skill in the art would not know how to use the claimed invention. These rejections are hereby withdrawn in view of Applicant's cancellation of claims 1-13 but are applied to new claims 15-19 and 24-28 as follows.

16. New claims 15-19, 24-28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility. This rejection is necessitated by amendment and is applied to new claims 15-19, 24-28 for the reasons of record and those set forth below.

17. Applicant argues that the Office fails to meet its burden in showing that the present application does not meet the utility requirements as set forth in 35 USC 101. Applicant refers to the Utility Examination Guidelines and points out that the Examiner has the burden of providing reasons as to why an asserted utility is "incredible". Applicant criticizes the teachings of Lucentini as not providing any information that relates directly to the invention. In addition, Applicant criticizes the study of Tan et al. as (1) being too small, (2) drawing conclusions from an unspecified Caucasian population, (3) using Hispanics as controls but not as cases. Applicant also submits that Tan et al. concludes that independent replication of the Swedish study is needed and that Tang et al. also state that a common "founder" effect may be present in a particular race. Applicant submits that while differences in the abundance of alleles in different populations may exist, this difference may be independent of the effect of the A1 allele on Parkinson's disease, and is a significant factor in the interpretation of the data of Tan et al. Applicant asserts that Tan et al. failed to find a correlation between the ADH7 mutations and disease due to methodological considerations. Applicant points out that even if the ADH7 mutations have a relatively minor effect relative to an aggregation of Parkinson's samples from all over the world, they may still be

vital to subgroups as diagnostic tools. Applicant argues that the claims are directed to sequences that have been correlated to a known disease and methods for diagnosing the disease. Thus, it is Applicant's contention that the instant case does not fall within the examples cited in MPEP 2107.01 and that a "real world" use is supported by the present disclosure.

18. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection of new claims 15-19, 24-28. New claims 15-19 and 24-28 are directed to nucleic acids consisting of one or more of SEQ ID NO: 1-7, and kits comprising said nucleic acids. The Examiner acknowledges the Utility Examination Guidelines and agrees that the Examiner has the burden of providing a prima facie showing of no specific, substantial, credible or well-established utility. However, the Examiner disagrees with Applicant's contention that the Office has failed to meet its burden in showing that the claimed invention does not meet the utility requirements set forth in 35 USC 101. First, it is noted that the analysis which led the Examiner to conclude that the claimed invention lacks patentable utility did not include any assessment as to whether or not the asserted utility is credible. The analysis was based solely on whether or not the claimed invention has a specific and substantial or well-established utility.

With regard to the teachings of Lucentini, while it is agreed that Lucentini does not refer specifically to the ADH7 polymorphisms of the instant application, the teachings of Lucentini are relevant to the issue of utility to the extent that they show that the claimed invention lacks substantial utility. As previously indicated, Lucentini (The Scientist 18(24):20, 2004) teaches that initial studies showing strong gene-disease associations based on statistical correlations, may provide a wrong association once all the data is carefully reviewed (page 20, first two paragraphs). A couple of studies have shown that when a finding is first published linking a given gene with a complex disease, there is only a one-third chance that studies will reliable confirm the finding (page 20, third paragraph). In the instant case, the conclusion regarding the association between the instant polymorphisms and Parkinson's

disease is based solely on statistical correlations. The specification is completely silent with regard to how these mutations correlate with Parkinson's disease, or how they are responsible for the corresponding symptoms. No information has been provided as to whether these polymorphisms are applicable to other populations or if the statistical correlation of alleles A1 and A3 is applicable to other populations. In addition, Applicant has not provided evidence that the presence of A1 and A3 in the population tested is sufficient to cause symptoms. Thus, in view of the teachings of Lucentini regarding the unpredictability of linking polymorphisms with disease based solely on statistical correlations, and the lack of evidence providing further support to a link between the disclosed polymorphism and Parkinson's disease, one of skill in the art would have to conduct further experimentation to reasonably confirm such link.

Applicant's criticisms to the study of Tan et al. are acknowledged but are not deemed persuasive. As previously indicated, Tan et al. (Neuroscience Letters 305 :70-72, 2001) teach that there is no significant association between the ADH7 A1 allele and an increased risk of Parkinson's disease (page 71, column 1, last paragraph). Their study contradict the results of (1) a Swedish study by Buervenich et al. (cited in the previous Office action) which found an association between the ADH A1 allele and risk of developing Parkinson's disease, and (2) Applicant's study which is the same study disclosed by Buervenich et al. In the absence of additional experimental data supporting Applicant's assertion regarding a link between Parkinson's disease and the disclosed polymorphisms, the teachings of Tan et al. are opposing evidence to the assertion of a link between Parkinson's disease and the disclosed polymorphisms. Thus, it would require additional experimentation for one of skill in the art to determine whether the disclosed polymorphisms are in fact markers for Parkinson's disease, such that they can be used as diagnostic tools, which is the asserted utility. This requirement for additional research is also supported by the teachings of Tan et al., as Tan et al., as correctly pointed out by Applicant, clearly discuss the need for independent replication of the Swedish study within the Swedish and other ethnic populations (page 72, left column, last paragraph).

Applicant's arguments regarding Tan's statements indicating that the ADH A1 polymorphism may have a "founder" effect in a particular race (page 72, left column, lines 12-13), and Applicant's assertion regarding the use of the disclosed polymorphisms as diagnostic tools for specific subgroups are acknowledged. The Examiner is not discarding the possibility that the ADH7 polymorphisms disclosed are race/subpopulation-specific. However, neither the art nor the specification provide any information as to the specific subpopulation associated with these polymorphisms. Thus, additional research is required to determine (1) whether these polymorphisms are indeed indicative of Parkinson's disease, and (2) which populations can be tested for risk of developing Parkinson's disease with these polymorphisms.

With regard to Applicant's criticisms regarding the size of Tan's study, the use of unspecified Caucasian individuals, and the use of Hispanics as controls only, it is worth noting that (1) Applicant's own study is smaller in size and restricted to a more specific population (Swedish); the study of Tan et al. comprised 100 PD patients, 100 diseased controls, and 194 healthy controls (Caucasian and Hispanic), whereas Applicant's study comprised 58 patients and 130 controls, (2) Tan et al. use 100 controls that are also similar in age, gender and race (Caucasian; page 70, right column, lines 4-11) to the 100 Parkinson's disease patients, and (3) Hispanics (94 controls) are not used as cases because they are an additional control in the study of Tan et al. It is also noted that Tan et al. addressed the issue of sample size and concluded that while a larger sample size could have been better in detecting smaller differences between the comparison groups, the low frequency of the A1 allele in the Swedish study (2 occurrences) and Tan's study (none) seem to suggest that this allele does not have a strong etiologic importance (page 72, left column, lines 1-6).

As discussed in the Non-Final action mailed on 5/8/2006, there is no consensus in the current state of the art as to the role of ADH7 gene or its alleles/polymorphisms in Parkinson's disease. This is evidenced by the contrasting results found by Buervenich et al. (Swedish study; cited in the previous Office Action) and Tan et al. While it is agreed that Applicant has provided a specific utility for the

claimed nucleic acids and kits, this utility is not considered substantial because it would require further research to identify or reasonably confirm a "real world" context of use. See e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Further experimentation is required to determine (1) whether these polymorphisms are indicative of Parkinson's disease, and/or (2) which populations can be tested for Parkinson's disease with these polymorphisms, if indeed these polymorphisms are associated with Parkinson's disease. Even the art, as evidenced by Tan et al., teach that additional research is required to find out whether there is an association between ADH polymorphisms and Parkinson's disease. In addition, Lucentini teaches that, in general, additional experimentation beyond a mere statistical correlation is required to determine whether a polymorphism is indicative of disease. Thus, contrary to Applicant's assertions, the Office has met its burden in showing that the claimed invention lacks patentable utility. In view of the teachings of the specification and those of the art, one cannot reasonably conclude that the asserted utility for the claimed nucleic acids and kits is substantial or well-established. Since the instant specification does not disclose a substantial "real world" use or a well-established use for the nucleic acids of SEQ ID NO: 1-7, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

19. New claims 15-19, 24-28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph

20. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

21. Claims 1-4 and 6-13 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of Applicant's cancellation of claims 1-4 and 6-13, this rejection is hereby withdrawn.

22. Claims 1-4 and 6-13 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for (1) nucleic acids comprising one or more of SEQ ID NO: 1-7 or SEQ ID NO: 2-7, (2) variants of the nucleic acids of (1), (3) kits comprising any means to detect the nucleic acids of (1), (4) isolated and non-isolated host cells comprising the nucleic acids of (1), or (5) expression vectors comprising the nucleic acids of (1). In view of Applicant's cancellation of claims 1-4 and 6-13, this rejection is hereby withdrawn.

23. Even if a specific and substantial utility or well established utility is found for the nucleic acids of SEQ ID NO: 1-7, the following rejection applies. New claims 15-19, 24, 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, even if enabling for nucleic acids consisting of one of SEQ ID NO: 1-7, does not reasonably provide enablement for nucleic acids consisting of two or more of SEQ ID NO: 1-7, or kits comprising said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is necessitated by amendment.

24. Applicant argues that this rejection does not apply to the new claims in view of the amendments introduced.

25. The Examiner acknowledges the amendments to the claims but disagrees with Applicant's contention that the full scope of new claims 15-19, 24, 27-28 is enabled by the teachings of the specification. New claims 15-19, 24, 27-28 encompass (1) nucleic acids consisting of one or more of SEQ ID NO: 1-7, and (2) kits comprising said nucleic acids. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation. The enablement provided is not commensurate in scope with the claims due to the fact that the specification fails to disclose how to use nucleic acids consisting of

combinations of SEQ ID NO: 1-7, as encompassed by the term "one or more of SEQ ID NO: 1-7". While the specification discloses a specific use for nucleic acids consisting of one of SEQ ID NO: 1-7, there is no teaching in the specification disclosing a correlation between Parkinson's disease and a nucleic acid which is a combination of any one of SEQ ID NO: 1-7, as encompassed by the claims. The specification also fails to disclose whether nucleic acids which are combinations of SEQ ID NO: 1-7 are protein encoding nucleic acids, and the biological activity of proteins encoded by said nucleic acids. In the absence of some knowledge or guidance as to which of the nucleic acid combinations can be used as diagnostic tools for Parkinson's disease, or the biological activity of those nucleic acid combinations claimed, one of skill in the art would have to test a large number of nucleic acids to determine how to use them. While enablement is not precluded by the necessity for routine experimentation, if a large amount of experimentation is required, as is the case herein, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

26. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

27. Claims 1-3, 6-8, 11-12 were rejected under 35 U.S.C. 102(a) as being anticipated by (1) Sage-Ono et al. (Plant Physiol. 116:1479-1485, April, 1998; GenBank accession number D85101, May 2, 1998), which disclose mRNA comprising all of SEQ ID NO: 2, (2) Carson et al. (GenBank AA080645, October 28, 1997), which disclose an EST which comprising all of SEQ ID NO: 4, and (3) NCI-CGAP

(GenBank accession number AA906249, May 19, 1998), which discloses a human EST that comprises all of SEQ ID NO: 7. In view of Applicant's cancellation of claims 1-3, 6-8, 11-12 and the fact that new claims 15-17 and 24-26 are directed to nucleic acids consisting of one or more of SEQ ID NO: 1-7, nucleic acids consisting of SEQ ID NO: 6, and nucleic acids consisting of SEQ ID NO: 3, these rejections are hereby withdrawn.

28. Claims 1-2, 6-8, 11-12 were rejected under 35 U.S.C. 102(b) as being anticipated by (1) Zgombic-Knight et al. (J. Biol. Chem. 270:4305-4311, 1995), which disclose the complete genomic structure of the ADH7 gene that encodes the human class IV alcohol dehydrogenase and disclose SEQ ID NO: 1, (2) Yokoyama et al. (Biochemical and Biophysical Research Communications 212(3):875-878, 1995; GenBank accession number L39009, March 7, 1996) which disclose a polynucleotide that comprises all of SEQ ID NO: 1, (3) Glass et al. (GenBank accession number U30500, September 1, 1995) which disclose a polynucleotide that comprises all of SEQ ID NO: 3, (4) King et al. (GenBank accession number L41145, April 1, 1995) which disclose a polynucleotide that comprises all of SEQ ID NO: 5, and (5) Mathews et al. (American Journal of Physiology 268:C1207-C1214, 1995; GenBank accession number U17249, September 27, 1995) which discloses mRNA that comprises all of SEQ ID NO: 6. In view of Applicant's cancellation of claims 1-2, 6-8, 11-12 and the fact that new claims 15-17 and 24-26 are directed to nucleic acids consisting of one or more of SEQ ID NO: 1-7, nucleic acids consisting of SEQ ID NO: 6, and nucleic acids consisting of SEQ ID NO: 3, these rejections are hereby withdrawn.

Claim Rejections - 35 USC § 103

29. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

30. Claims 7-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over (1) Glass et al. (GenBank accession number U30500, September 1, 1995), and (2) King et al. (GenBank accession number L41145, April 1, 1995). In view of Applicant's cancellation of claims 7-8 and the fact that new claims 15-17 and 24-26 are directed to nucleic acids consisting of one or more of SEQ ID NO: 1-7, nucleic acids consisting of SEQ ID NO: 6, and nucleic acids consisting of SEQ ID NO: 3, these rejections are hereby withdrawn.

31. Claims 9-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over (1) Zgombic-Knight et al. (J. Biol. Chem. 270:4305-4311, 1995), (2) Yokoyama et al. (Biochemical and Biophysical Research Communications 212(3):875-878, 1995; GenBank accession number L39009, March 7, 1996), (3) Glass et al. (GenBank accession number U30500, September 1, 1995), (4) King et al. (GenBank accession number L41145, April 1, 1995), (5) Mathews et al. (American Journal of Physiology 268:C1207-C1214, 1995; GenBank accession number U17249, September 27, 1995), (6) Sage-Ono et al. (Plant Physiol. 116:1479-1485, April, 1998; GenBank accession number D85101, May 2, 1998), (7) Carson et al. (GenBank AA080645, October 28, 1997), and (8) NCI-CGAP (GenBank accession number AA906249, May 19, 1998). In view of Applicant's cancellation of claims 9-10 and the fact that new claims 18-19 and 27-28 are directed to kits comprising nucleic acids consisting of one or more of SEQ ID NO: 1-7, these rejections are hereby withdrawn.

Double Patenting

32. Applicant is advised that should claims 15, 18 and 19 be found allowable, claims 24, 27 and 28 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a

substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 24 is identical to claim 15, claim 27 is identical to claim 18, and claim 28 is identical to claim 19.

Conclusion

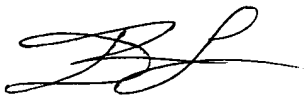
33. No claim is in condition for allowance.

34. Applicant's amendment adding new claims 15-32 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 9, 2006